JEIL MEDICAL CORPORATION
#702, Kolon Science Valley 2nd, 811
Guro-Dong, Guro-Gu, Seoul, 152-050 Korea
Tel : +82 2 850 3500 / Fax : +82 2 850 3535

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92(c).

Date: May 28, 2013

1. Company and Correspondent making the submission:

	Company
Name	Jeil Medical Corporation
Address	#702, Kolon science valley 2nd 811, Guro-Dong, Guro-Gu Seoul, Republic of Korea 152-050
Phone	+82 2 850-3524
Fax	+82 2 850-3525
Contact	Jieun Kim

2. Device:
   Proprietary Name – ARIX Hand System
   Common Name – Bone plate & screw
   Classification Name – Single/multiple component metallic bone fixation appliances and accessories

3. Predicate Device:
   Profyle System, K062498, Howmedica Osteonics Corp.

4. Classifications Names & Citations:
   Orthopedic
   HRS, 21CFR888.3030

5. Description:
   The ARIX Hand System is designed to fixation of the bones of hand and wrist. Examples of these procedures may include but are not limited to replantation, lag screw techniques, joint fusions, corrective osteotomies, and the treatment of fractures. The ARIX Hand System consists of the ARIX Hand System Plate and the ARIX Hand System Screw. The ARIX Hand System Plate is made of Pure Titanium (ASTM F67) and the ARIX Hand System Screw is made of the Titanium Alloy (ASTM F136). This device performance is not adversely affected by aging or storage conditions since this device is to be sterilized at the hospital before use and also to be single use.

6. Indication for use:
   The ARIX Hand System is intended for use in internal fixation of the bones of hand and wrist. Examples of these procedures may include but are not limited to replantation, lag screw techniques, joint fusions, corrective osteotomies, and the treatment of fractures.

7. Review:
   The ARIX Hand System has the similar device characteristics as the predicate device, the Profyle System, K062498, Howmedica Osteonics Corp.; intended use, materials, design and use concept.

JEIL MEDICAL CORPORATION
#702, Kolon Science Valley 2nd, 811
Guro-Dong, Guro-Gu, Seoul, 152-050 Korea
Tel : +82 2 850 3500 / Fax : +82 2 850 3535

sterilization, etc. Only the technical specifications –bending strength, bending stiffness, tensile strength, driving torque, torsion and pullout – are slightly different.

The following tests were performed with the predicate device:

•Plates
- Bending Strength test per ASTM F382
- Tensile Strength test

•Screw
- Driving torque test ASTM F543
- Torsion test ASTM F543
- Axial Pullout Strength per ASTM F543

Based on the comparison of intended use and technical features, the ARIX Hand System is substantially equivalent to the predicate devices.

8. Conclusions:
   In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Jeil Medical Corporation concludes that the ARIX Hand System are substantially equivalent to predicate devices as described herein.

9. Jeil Medical Corporation will update and include in this summary any other information deemed reasonably necessary by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 4, 2013

Jeil Medical Corporation
Mr. Ji-Eun Kim
Regulatory Affairs Manager
Number 702, Kolon Science Valley 2nd 811
Guro-Dong, Guro-Gu
Seoul-City 152-050
Republic of Korea
South Korea

Re: K131566
Trade/Device Name: ARIX Hand System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: October 16, 2013
Received: October 17, 2013

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin L. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

JEIL MEDICAL CORPORATION
#702, Kolon Science Valley 2nd, 811
Guro-Dong, Guro-Gu, Seoul, 152-050 Korea
Tel : +82 2 850 3500 / Fax : +82 2 850 3535

Indications for Use

510(k) Number (if known): K131566

Device Name: ARIX Hand System

Indications for Use:

The ARIX Hand System is intended for use in internal fixation of the bones of hand and wrist. Examples of these procedures may include but are not limited to replantation, lag screw techniques, joint fusions, corrective osteotomies, and the treatment of fractures.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices